

### **REMARKS/ARGUMENTS**

Applicants thank the Examiner for his time in the interview held at the Patent Office on August 28, 2003. The interview was very helpful in advancing the prosecution of this application, and applicants have prepared these Preliminary Remarks in accordance with the discussions held during the interview.

Applicants reviewed the Siedel reference in greater detail following the interview, and continue to believe that Siedel is significantly different than the claimed invention. Siedel is directed to methods of eliminating interference due to the presence of hemoglobin. The methods require the use of bleaching reagents to eliminate the interference. In stark contrast, the claimed invention does not utilize bleaching reagents to accomplish a reduction in hemoglobin interference. Rather, the claimed invention functions to account for background color in a sample that might be due to the presence of hemoglobin. Thus, the claimed invention functions to blank any interference due to hemoglobin, while the methods of Siedel function to bleach any such interference.

As the Examiner has indicated, Siedel does discuss the use of blanks in the disclosed methods. For example, in column 3, lines 25-45, Siedel discusses blank value corrections that are determined on a sample that includes both the R1 and R2 reagents (as discussed below and listed in Siedel, R2 is 4-nitrophenyl phosphate). At the interview, the Examiner agreed that this language is somewhat confusing, and its meaning is not readily apparent.

At the Examiner's suggestion, the inventors of the present application have reviewed the language to determine its proper meaning. The inventors have reviewed this section of Siedel, and do not believe that any translation error has been introduced. They believe that this section of Siedel means exactly what it says – that a blank can be performed on a sample that includes *both R1 and R2*. By reading Example 1 of Siedel, this language is further clarified, and a distinction between it and the claimed invention becomes more clear. In describing the blanking procedure, Siedel states that:

A further hemoglobin bleaching which may still underly the colour formation from the chromogenic substrate during the measurement interval can be determined by additionally measuring *a separate reaction mixture with chromogen-free R2* (=R1 from the basic reagent) and using this to correct the AP activity.... (column 5, lines 57-62) (emphasis added).

In section 1.2 of the Example, R2 is listed as 4-nitrophenylphosphate. Thus, review of Siedel makes it clear that the blanking procedure is conducted on a sample following the addition of 4-nitrophenylphosphate. *In contrast, the invention claimed in the present application measures a blank value before the addition of 4-nitrophenyl phosphate.*

Applicants have also had an additional translation prepared from the original German Siedel application. Appendix A presents this translation for the text that corresponds to column 3, lines 25-45 of the United States patent (6,013,467). While this translation has some minor differences from that in the '467 patent, the language also makes it clear that the blanking procedure is conducted on a sample following the addition of 4-nitrophenylphosphate, in contrast to the present application.

Accordingly, Siedel does not disclose each and every limitation of any claim of the present application, and cannot, therefore, properly serve as a basis for rejection.

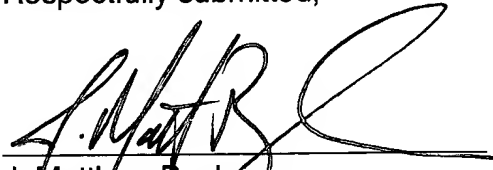
### **CONCLUSION**

In light of the above, Applicants have overcome each and every one of the Examiner's rejections. The application is therefore in condition for allowance on the next Office action. If, however, the Examiner feels that further personal communication would

Application No. 09/807,079  
Amendment dated September 15, 2003  
Reply to Office action dated June 13, 2003

facilitate the prosecution of this case, applicants request that the Examiner contact their attorney at the number listed below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "J. Matthew Buchanan", written over a horizontal line.

J. Matthew Buchanan  
Registration No. 47,459  
Attorney for Applicant

Dated: September 15, 2003

BRINKS HOFER GILSON & LIONE  
P.O. BOX 10395  
CHICAGO, ILLINOIS 60610  
(312) 321-4281



## Appendix A

**Translation of text from original Siedel German application that corresponds to column 3, lines 25-45, in US 6,013,467.**

If, on the other hand, the bleaching reaction has not yet reached a standstill when the measurement begins—which can be the case if the sample contains a very high concentration of hemoglobin and/or if the sample-to-reagent volume ratio is relatively high—another blank value correction can preferably be carried out in order to attain the desired analytical accuracy. Said blank value correction can be carried out, for example, by subtracting the blank value signal from the measuring signal. The measuring signal is obtained using the reagent that contains peroxide and chromogen, but the blank value signal was obtained in the same measurement period in a parallel reaction solution using the reagent that also contains peroxide, but no chromogen. Particularly preferably, the blank value correction is carried out by subtracting a kinetic blank value.

In a two-step test, the blank value is preferably carried out by adding a first, peroxide-containing, partial reagent (R1)—preferably a reagent having the same peroxide concentration as the reaction solution—then adding a chromogen-free, second partial reagent (R2) to the sample, and then, out of this reaction solution, determining the blank value to be subtracted from the measuring signal.

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